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Total Number of Pages in This Submission

Application Number	09/980,062
Filing Date	05/10/02
First Named Inventor	A. Satyanarayan Naidu
Art Unit	1654
Examiner Name	Russell, Jeffrey E.
Attorney Docket Number	50046290-0007 (US-PCtT106099)

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
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  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☑ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Reply to Examiner's Answer Mailed April 24, 2006

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Jackson, DeMarco, Tidus & Peckenpaugh		
Signature	Paul D. Chancellor		
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Date	June 26, 2006	Reg. No.	52,715

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Signature	Paul D. Chancellor		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 09/980,062

Filed: May 10, 2002

Applicant: Naidu, Satyanarayan A.

For: IMMOBILIZED LACTOFERRIN (Im-LF) ANTIMICROBIAL AGENTS AND USES THEREOF

Atty. Dkt.: 50046290-0007

Examiner: Russel, Jeffrey E.
Group Art Unit: 1654

REPLY TO EXAMINER'S ANSWER MAILED APRIL 24, 2006
Appeal of Final Office Action of January 5, 2006

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Sir:

Applicant provides herein its reply to the Examiner's Answer mailed April 24, 2006.

I. The Examiner Has Failed To Meet His Burden

A. Standard For Rejection

The Examiner has the burden of producing a factual basis for each ground for rejection of the claims on appeal. *In re Piaseki*, 745 F.2d 1468, (Fed. Cir. 1984). Rejections for anticipation require the Examiner to show "clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (citing *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976F.2d 1559, 1565 (Fed. Cir. 1992). And rejections for obviousness require the Examiner to show prior art "disclos[ing] all the limitations of the claims" and "motivation to combine." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333 (Fed. Cir. 2003) (referring also to *In re Royke*, 490 F.2d 981, 985 (CCPA 1974) (obviousness requires a suggestion of all limitations in a claim)). Only when the Examiner has made a *prima facie* case of unpatentability does the burden of coming forward with evidence or arguments shift to the applicant. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

B. Standard For Inherent Anticipation

All of the Examiner's prior art rejections are based on inherency. (Examiner's Reply, page 10.) The Federal Circuit has set forth and recently reaffirmed the standards for inherency in *SmithKline v. Apotex*, 403 F.3d 1331, 1343 (Fed. Cir. 2005):

> A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is **necessarily present**, or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

(Bold added.)

II. **No *Prima Facie* Case Establishing That Immobilized Lactoferrin Is Formed**

The Examiner correctly acknowledges that "none of the references describe compositions in terms of lactoferrin (LF) binding via its N-terminus region to a substrate." (Examiner's Answer, p. 10.) However, the Examiner is incorrect and has failed to meet his burden to establish that "the prior art references teach the same components present in the same types of compositions as are claimed by Appellants (sic)." (Examiner's Answer, p. 11.)

As explained in Applicant's Second Replacement Appeal Brief the references variously fail to disclose the same components or the same types of compositions. For example, WO Patent Application '982, European Patent Application 753,308, European Patent Application 753,309 and U.S. Pat. No. 6,066,469 fail to disclose a component capable of immobilizing LF via the N-terminus region of the LF. WO Patent Application '982, U.S. Pat. No. 6,066,469 and U.S. Pat. No. 6,475,511 fail to disclose a suitable technique whereby LF would become immobilized via the N-terminus region of the LF even if a naturally occurring component capable of serving as a substrate for immobilizing LF were present, and all of the references fail to disclose a composition of LF immobilized via the N-terminus region of the LF on a naturally occurring substrate.

Arguing that the claimed immobilized LF is inherently anticipated by the references, the Examiner relies on *Atlas Powder Co. v. Irelco Inc.*, 190 F.3d 1342 (Fed. Cir. 1999) for the proposition that:

> [T]he discovery of a previously unappreciated **property** of a **prior art composition**, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. (*Id.*at 1347.)

(Bold Added.)

However, implicit in this proposition is the requirement that the claimed composition be the same as the composition found in the references. *Atlas* is therefore misapplied here by the Examiner since as shown by the Applicant, the compositions of WO Patent Application '982, European Patent Application 753,308, European Patent Application 753,309 and U.S. Pat. No. 6,066,469 disclose different compositions than the claimed immobilized LF compositions.

Moreover, also implicit in this proposition is that the prior art actually possessed the claimed property or characteristic and further that such was inherent in the prior art. But, the Examiner makes no showing here that the claimed immobilized LF is inherently produced by practicing the prior art. And as the *SmithKline* court makes clear, where there is "no positive evidence" showing that "practice[ing] the [prior art] patent results in the production of the claimed [composition]" a court properly finds "no anticipation." *SmithKline v. Apotex*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (quoting from *In re Seaborg*, 328 F.2d 996 (CCPA 1964)). Because there is no positive evidence showing that practicing the prior art references inevitably results in the production of the claimed immobilized LF, the references do not inherently anticipate any of the claims on appeal.

The Examiner's reliance on *Best* as a basis for drawing an inference of lack of novelty fails for similar reasons. *In re Best*, 562 F.2d 1252 (CCPA 1977). In *Best*, the applicant made product and process claims to a catalyst having SiO2/Al2O3 and Na2O/Al2O3 in respective

molar ratios. The prior art disclosed a composition having identically SiO2/Al2O3 and Na2O/Al2O3, within the same molar ranges claimed by the applicant.

Quoting from *Best*:

> Where, as here, the claimed and prior art **products are identical** or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. (*Id.*at 1255) (quoting from *In re Ludke*, 441 F.2d 660 (CCPA 1971)).

(Bold Added.)

Unlike the identical products in *Best* or even the substantially identical products that might provide sufficient grounds in another case, the Examiner here states that "[s]ufficient evidence of similarity is deemed to be present..." to support a *prima facie* case of inherent anticipation. This is not the standard articulated in *Best.* With respect to such core factual findings in a determination of a lack of patentability, the Examiner cannot simply reach conclusions based on his own understanding or experience or on his assessment of what would be basic knowledge or common sense. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001.) Instead, the Examiner must point to sume concrete evidence in the record to support the findings underlying the rejections. (*Id.*) And the Examiner's factual basis here falls even shorter of the standard recently articulated by the *SmithKline* court requiring "positive evidence" the missing characteristic would invariably be produced before approving of a finding of inherent anticipation. *SmithKline v. Apotex*, 403 F.3d 1331, 13463 (Fed. Cir. 2005). Because the Examiner has failed to meet his burden, the rejection of all the claims on appeal should be withdrawn.

III. Applicant's Evidence Overcomes Alleged *Prima Facie* Case

Furthermore, Appellant has submitted ample evidence to demonstrate that none of the references inherently disclose the claimed immobilized LF. But, the Examiner continues to

improperly refuse to address the substance of the declaration of Dr. Andrew Barron. The Examiner maintains that the declaration can be dismissed, because it is "unsupported by evidence of direct testing of the prior art compositions." (Examiner's Answer, p. 10.) However, the Examiner cites no authority in support of his dismissal. And, on the contrary, the case law clearly supports just the opposite. (See, for example, *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (holding that the Examiner had erred in dismissing a declaration based on "statements of fact."))

Similarly, the Examiner cites no authority for his proposition that a declaration must be supported by the specification (*Id.*) or even that the declaration must not be contradicted by the specification (*Id.*) . Whatever effect, in an appropriate situation, these factors might have on the *weight* to be afforded a declaration, they do not provide an excuse for *utterly ignoring* a declaration. Here, the Examiner has failed to provide any substantive reasons for refusing to consider the substance of Dr. Barron's declaration. Dr. Barron's declaration has a well founded factual basis (and one that is entirely consistent with the disclosure set forth in applicant's specification.) Accordingly, it is persuasive on the issue of whether any of the references relied upon by the Examiner inherently disclose LF immobilized on a naturally occurring substrate via the N-terminus region of the LF.

As explained by Dr. Barron, the reasons that immobilization cannot occur are because (1) the "substrates" are too small to immobilize LF, (2) the "substrates" do not possess the proper

charge to bind LF's positively charged N-terminus or (3) the proper conditions for immobilization are not described.

The Examiner argues that:

> With respect to contention [1] Appellants and Declarant argues [sic] that the stearic acid of the WO Patent Application '892; the paraffin oil, Vaseline, and lecithin of the European Patent Application '309; and the peppermint oil of the European Patent Application '308; can not serve as substrates because of their low molecular weights. See paragraphs 17, 23, 27, and 30 of the declaration. This argument can not be accepted because it contradicts the original disclosure of substrates with molecular weights significantly less than that of lactoferrin. Further, Appellants continue to claim substrates (e.g., the nucleotide of claim 2, and the adenosine triphosphate of claim 3) which are of a size that Appellants and Declarant argue are too small to serve as substrates. When arguments made by Appellants or by Declarant contradict those made in the originally-filed application or in the claims, the latter preponderate.

The Examiner does not suggest that, as a matter of scientific fact, the "substrates" disclosed in these references are not too small to immobilize lactoferrin." The Examiner argues only that appellant should be estopped from making such an argument, because the application originally listed certain, inoperative species. The Examiner, however, provides no legal support for a rule that, if followed, would result in an applicant forfeiting otherwise patentable subject matter. To the contrary, the court in *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) stated "[i]t is

not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim... ." Further, given that appellant has established that, as a matter of scientific fact, none of these references (inherently) disclose immobilized LF, the references cannot properly be relied upon to anticipate or make obvious appellants claims to immobilized LF.

Appellant appreciates that claims 2 and 3, claims that still list inoperative species, might be subject to a rejection under 35 U.S.C. § 112. Consequently, appellant previously tried to amend these claims to cancel the inoperative species. (Applicant's Proposed Amendment Dated August 29, 2005.) The Examiner, however, refused to enter the amendment. (Office Action Mailed September 13, 2005.) It is appellants intention to resubmit these amendments upon conclusion of this appeal.

The Examiner argues that with respect to contention [2]:

> Appellants and Declarant state that '[f]or the N-terminus region to become immobilized on a naturally occurring substrate, the region of the substrate to which the N-terminus region is to become attached should carry the opposite charge, i.e., carry a negative charge.' See the declaration at paragraph 9, and also paragraphs 25, 26, 31, and 36. However, Declarant does not provide any citation to the specification which would support this contention, and the Examiner can find no support in the original disclosure of the invention for this contention. Further, this argument is inconsistent with the

> disclosure of the specification of useful substrates which do not have a positive charge. For example, the original specification at page 10, line 22, and originally-filed claim 3 disclose triglycerides to be useful substrates for immobilizing lactoferrin by its N-terminus region. Triglycerides are uncharged. The original specification at page 10, lines 19-22, and originally filed claim 3 disclose proteins, polysaccharides, and lipids to be useful substrates for immobilizing lactoferrin by its N-terminus. These classes of compounds embrace positively charged, negative [sic] charged, and uncharged compounds. To the extent that the opinions set forth in the declaration are contradicted by the specification, they can not be relied upon to rebut the prima facie case of anticipation.

Again, the Examiner does not suggest that, as a matter of scientific fact, the "substrates" disclosed in these references have the proper charge to immobilize LF. The Examiner argues only that appellant should be estopped from making such an argument, because the application originally listed certain, inoperative species. The Examiner, however, provides not legal support for a rule that, if followed, would result in an applicant forfeiting otherwise patentable subject matter. To the contrary, the court in *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) stated "[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim... ." Further, given that appellant has established that, as a matter of scientific fact, none of these references (inherently) disclose immobilized LF, the references cannot properly be relied upon to anticipate or make obvious appellants claims to immobilized lactoferrin.

Finally, the Examiner argues with respect to contention [3]:

> Appellants [sic] and Declarant argue that mixing, compounding, and cold pressing as occur in "Gohlke et al, the WO Patent Application '982, and Kruzel et al will not provide an environment suitable to cause the lactoferrin to become attached to a substrate via the lactoferrin N-terminus region. However, Declarant does not provide any reasoning or evidence as to why these processing steps are insufficient to result in immobilization via the N-terminus of lactoferrin. See paragraphs 13, 14, 19, 20, 35, 37, and 38 of the declaration. Further, there is no disclosure anywhere in the specification that special procedures or conditions are necessary in order to achieve the desired immobilization. See, e.g., page 11, lines 3-11, of the specification."

The Examiner ignores that the specification teaches that LF is immobilized on the substrate, not by any technique, but by a "suitable" technique. (Specification page 11, lines 3-5.) The specification discloses as a suitable, read special, technique "mixing LF with the biologically active substrate in a suitable medium, such as deionized water." (*Id.*) The declaration of Dr. Barron then goes on to explain why none of the references discloses a suitable technique. None of the references discloses mixing in suitable medium. Instead, solid LF is simply admixed with a solid substrate. As explained, by Dr. Barron, under such circumstances, immobilization cannot occur. As Dr. Barron states, "Merely compounding solid LF with other solids, such as stearic acid, will not provide an environment suitable to cause the LF to become attached to the other

solid via LF's N-terminus region." (Barron Decl., ¶ 11.) And, "Merely compounding solid LF with other solids, will not provide an environment suitable to cause the LF to become attached to the other solid via its N-terminus region." (Barron Decl., ¶ 38.)

Dr. Barron uses this principal as the basis for his conclusion that the references did not disclose suitable conditions to cause the immobilization of lactoferrin. In paragraph 13, in his discussion of Gohlke *et al.*, Dr. Barron explains, "the mere presence of LF in a cold-pressed mixture with other solids, such as colostum and modified pectin in an MDF format would not inherently result in the LF becoming attached via its N-terminus on a substrate." In paragraph 20, in his discussion of '982, Dr. Barron explains, "Merely compounding solid LF with other solids, such as stearic acid, will not provide an environment suitable to cause LF to become attached to the other solid via LF's N-terminus region." In paragraph 34, in his discussion of Kruzel, Dr. Barron explains, The mere presence in a mixture of LF and an adjuvant or a diluent, such as the solids cellulose, starch, tragacanth, and sodium carboxymethylcellulose would not inherently result in the LF becoming attached via its N-terminus."

The Examiner attempts to rebut Dr. Barron's declaration on the ground that:

Assuming arguendo that a substrate must be negatively charged in order for the N-terminus of lactoferrin to be immobilized (see Appellants' contention (4)), then because the stearic acid of the WO Patent '982 has a negatively charged carboxyl group, all that it would take for the positively charged N-terminus of lactoferrin to become immobilized

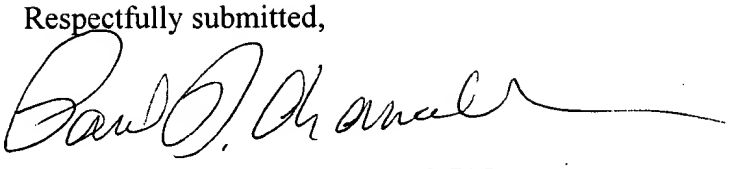
> on the negatively charged carboxyl group would be to bring the two opposite charges into close physical proximity – charge attraction will do he remainder of the work. Any pharmaceutical compounding step will provide the necessary physical proximity so that at least some of the lactoferrin is immobilized by its N-terminus to a [sic] least some of the stearic acid. Appellants' contention in contention (2) is thus refuted by Appellants' argument n contention (4).

The Examiner provides no evidence for these broad assertions. The law is clear that the Examiner cannot simply reach conclusions based on his own understanding or experience or on his assessment of what would be basic knowledge or common sense. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001.) Instead, the Examiner must point to some concrete evidence in the record to support the findings underlying the rejections. (*Id.*)

Therefore none of the references relied upon by the Examiner inherently disclose LF immobilized on a naturally occurring substrate via the N-terminus region of the LF and the rejection of all the claims on appeal should be withdrawn.

Dated: June 26, 2006

Respectfully submitted,



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